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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/519,118 | 09/29/2005 | Karl Lintner | SEDERM 3.3-009 | 9458 |
| 530 7590 11/04/2009 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090 | | | | |
| EXAMINER | | | | |
| GULLEDGE, BRIAN M | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1612 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/519,118

Applicant(s)

LINTNER, KARL

Examiner

Brian Guldge

Art Unit

1612

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-22 and 24-43 is/are pending in the application.
- 4a) Of the above claim(s) 22, 24, 30-37, 40, 42 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-21, 25-29, 38, 39 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Previous Rejections

Applicants' arguments, filed August 27, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112, New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-21, 25-29, 39, and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This is a "new matter" rejection. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 18 has been amended to recite that the cosmetic composition "consists essentially of" the subsequently recited ingredients. There is insufficient support for this limitation in the originally filed disclosure. The disclosure does not define or discuss any compositions as "consisting essentially of" any ingredients, does not define as "essential" any ingredients, and does not provide a clear

indication what the basic and novel characteristics actually are for the claimed invention. As such, the amendment is not supported by the originally filed disclosure.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 18-21, 25-29, 38-39, and 41 stand rejected under 35 U.S.C. 102(b) as being anticipated by Satoh et al. (European Patent Application 0189861). The Applicant argues that the rejection of the claims is not proper, as the claims now recite that the cosmetic consists essentially of the subsequently recited ingredients, and as such the combination of ingredients present in the embodiment disclosed by Satoh et al. is excluded by the claim language. The Applicant also argues that the rejection of claim 38 is not proper, as the claim recites a product and limitations directed to how the material was prepared. Applicant states that a recent court ruling (*Abbott Labs. v. Sandoz, Inc.*) decided that for infringement purposes that “process terms in product-by-process claims serve as limitations in determining infringement.” Applicant further argues that it is “unreasonable to have claims interpreted in different ways – one way for infringement and one way for patentability.” The Applicant further argues that the rejection is not proper as the dependent claim 39 requires an additional ingredient which reduces melanin.

The Examiner is not persuaded by these arguments. While claim 18 has been amended to recite that the composition consists essentially of an excipient and a compound of formula I, the specification does not provide a clear indication what the basic and novel characteristics actually are for the claimed invention, and as such the transitional phrase “consisting essentially of” will

be construed as equivalent to "comprising." See MPEP 2111.03. And Satoh et al. discloses a composition comprising an excipient and a compound of formula I. The Examiner also notes the court case cited relates to infringement, and not to prosecution of an application and the examination of claims. The MPEP still discusses product-by-process limitations, and how these limitations are to be examined (MPEP 2112), and until the MPEP is revised, an infringement ruling will not be relied upon to go against the practices set forth in the MPEP. Finally, the Examiner does not find that claim 39 recites an additional ingredient, the ingredient having the property of reducing melanin, but rather the claim recites the further limitation that an ingredient present has this property, which octopamine inherently possesses.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Gulledge whose telephone number is (571) 270-5756. The examiner can normally be reached on Monday-Thursday 6:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BMG

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612